HFI-35

EPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-30977
Telephone: (513) 679-2700
FAX: (513) 679-2761

May 13, 1999

WARNING LETTER
CIN-WL 99-248

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert W. Thomas
10835 Georgetown Road
Louisville, Ohio 44641

Dear Mr. Thomas:

The Food and Drug Administration (FDA) was informed by the USDA that tissue from a dairy cow, which you sent to slaughter on or around 10/14/98, was found to contain illegal drug residues. The USDA laboratory's analytical report #000161, determined that the liver, muscle and kidney tissues of the referenced animal contained Oxytetracycline at levels of: 4.50, 2.60, and 14.00 ppm, respectively. The muscle tissue of this animal was also found to contain Sulfadimethoxine at 2.10 ppm. The established tolerance levels for Oxytetracycline in these tissues are: 6.00, 2.00, and 12.00 ppm, respectively. The tolerance established for Sulfadimethoxine in muscle tissue is 0.1 ppm.

This cow was offered for slaughter as food in violation of Sections 402 (a)(2)(C)(ii), and 402 (a)(4) and Section 501 (a)(5) of the Federal Food, Drug, and Cosmetic Act (the Act). An investigation at your dairy operation conducted by our investigator on 1/25, 1/26, 3/5, 4/19 & 4/22/1999, determined that this cow belonged to you.

A food is adulterated under Section 402 (a)(2)(C) (ii) of the Act, if it contains a new animal drug which is unsafe within the meaning of Section 512 and Section 402 (a)(4) if the food has been held under insanitary conditions whereby it may have been rendered injurious to health. As it applies in this instance, "insanitary conditions", refers to your lack of records for animals which you medicate. Consequently, you held an animal, which was ultimately offered for sale for food, under conditions, which are so inadequate, that a medicated animal bearing possibly harmful drug residues was likely to enter the food supply. A drug is adulterated under Section 501 (a)(5) if it is administered in a manner other than in accordance with the directions specified in the labeling, thereby making it unsafe within the meaning of Section 512(a)(1)(B).

The above is not intended to be an all inclusive list of violations. Please notify this office within fifteen (15) working days of the receipt of this letter of the specific steps that you have taken to correct the noted violations. Your response should include an explanation of each step being taken to prevent the recurrence of similar violations in the future. If your corrective action can not be completed within 15 working days, please state the reason for the delay, and the time frame within which the necessary corrections will be completed.

Failure to promptly implement adequate corrections may result in further regulatory action such as seizure and/or injunction, without additional notice.

Your response should be directed to the U. S. Food and Drug Administration, Cincinnati District Office, 6751 Steger Drive, Cincinnati, Ohio 45237-3097, ATTN: David C. Radle, Tissue Residue Monitor.

Sincerely,

Henry L. Fielden
District Director
Cincinnati District